UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ERIKA HAWKINS,
JOHN M. CENTANNI,
JACQUELINE SANKBELL, and
KEITH V. WOOD

Appeal No. 2004-1904
Application No. 09/590,884

HEARD: January 11, 2005

Before WILLIAM F. SMITH, SCHEINER, and GRIMES, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1-57, all the claims in the application. Claims 1, 2, 3, and 22 are representative of the subject matter on appeal and read as follows:

1. A method for increasing the sensitivity of a bio-luminescent assay comprising carrying out the assay in the presence of an organic compound that reduces luminescence that is not dependent on the presence of an analyte by at least about 10 fold, and that reduces luminescence that is dependent on the presence of an analyte by less than about 7 fold.

2. A method for increasing the sensitivity of a luminescent assay comprising carrying out the assay in the presence of an organic compound that reduces luminescence generated by luminogenic molecules not bound to an enzyme by at least about 10 fold, and that reduces the luminescence generated by luminogenic molecules bound to an enzyme by less than about 7 fold.

3. A method for increasing the sensitivity of a bio-luminescent assay comprising carrying out the assay in the presence of an organic compound that reduces autoluminescence by at least about 10 fold, and that reduces luminescence that is dependent on the presence of an analyte by less than about 7 fold.

22. An assay kit comprising packaging material containing 1) a luminogenic substrate of a luminescent enzyme, or a luminogenic enzyme; and 2) an organic compound for reducing luminescence that is not dependent on the presence of an analyte by at least about 10 fold, and for reducing luminescence that is dependent on the presence of an analyte by less than about 7 fold.

The references relied upon by the examiner are:

Kricka	5,629,168	May 13, 1997
Wood	5,814,471	Sep. 29, 1998
Mitoma et al. (Mitoma) (Japanese Kokai Patent)	JP 07067696 A	Mar. 14, 1995

Claims 1-3, 8-12, 16-21, and 35-53 stand rejected under 35 U.S.C. § 103(a) with the examiner relying upon Mitoma as evidence of obviousness. Claims 1-3, 8-31, and 34-57 stand rejected under 35 U.S.C. § 103(a) with the examiner relying upon Kricka as evidence of obviousness. Finally, claims 1-57 stand rejected under 35 U.S.C. § 103(a) with the examiner relying upon Wood as evidence of obviousness.

In reviewing the issues raised in this appeal, we have come to the conclusion that claims 1-57 do not comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Accordingly, we enter a new ground of rejection under 37 CFR § 41.50(b) under 35 U.S.C. § 112, first paragraph (written description). Furthermore, in

reviewing the prior art rejections we find that neither the examiner nor appellants have considered the obviousness issues in light of the relevant legal standards. Thus, we vacate the three obviousness rejections.

Background

The present invention involves appellants' discovery that "the sensitivity of luminescence assays can be improved by carrying out the assay in the presence of one or more organic compounds that reduce analyte-independent luminescence." Specification, page 3. Appellants explain that "using procedures similar to those described herein, one skilled in the art can identify compounds that are suitable to increasing a sensitivity of a luminescence assay. The structure of the compound is not critical provided the compound is capable of increasing the sensitivity of a luminescence assay." Id., pages 9-10. Appellants also state that compounds that comprise a sulfur atom or a selenium atom are particularly useful, id., page 10, and that suitable compounds include organic compounds, especially organic compounds that comprise a carbon-sulfur bond or a carbon-selenium bond. Id.

Appellants provide a description of compounds that comprise a carbon-sulfur bond or a carbon-selenium bond. Id., pages 10-15. Appellants also state that preferred organic compounds exclude compounds including polypeptides and proteins that comprise one or more mercapto groups. Id., page 15. No compound that does not include a carbon-sulfur or a carbon-selenium group is specifically described.

New Ground of Rejection Under 37 CFR § 41.50(b)

Claims 1-57 are rejected under 35 U.S.C. § 112, first paragraph (written description).

Each of the claims on appeal requires the use or presence of an "organic compound." The organic compound used in the claimed invention is qualified only by a functional statement regarding the extent that luminescence that is not dependent on the presence of an analyte and luminescence that is dependent on the presence of an analyte are reduced. In Univ. of Calif. v. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), the court determined that a definition by function only indicates what the compounds do rather than what they are, stating "[i]t is only a definition of a useful result rather than a definition of what achieves that result." Id.

We find Eli Lilly to be particularly instructive here. Claims 1 and 2 of the '525 patent under review in Eli Lilly generically recited cDNA encoding vertebrate insulin while claim 4 was directed generically to cDNA encoding mammalian insulin. The only cDNA described in the '525 patent encoded rat insulin. The court held "a description of rat insulin cDNA is not a description of the broad classes of vertebrate or mammalian insulin cDNA." Eli Lilly, 119 F.3d at 1568, 43 USPQ2d 1405. The court noted in Eli Lilly that

> in claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.

Id., 119 F.3d at 1568, 43 USPQ2d 1406.

More recently, the court considered the written description requirement in relation to non-genetic material in University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004). After observing that "the statute applies to all types of inventions," the court stated "that functional descriptions of genetic material can, in some cases, meet the written description requirement if those functional characteristics are 'coupled with a known or disclosed correlation between function and structure, or some combination of some characteristics' ... (quoting from the PTO's Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 P1 'Written Description' Requirement, 66 Fed.Reg. 1099, 1106)." (internal citation omitted). The court also stated in University of Rochester, "[r]egardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods." Id., 358 F.3d at 926, 69 USPQ2d at 1894.

Applying these legal principles to the facts at hand, we conclude that the claims on appeal do not comply with the written description requirement of 35 U.S.C. § 112, first paragraph. As seen, all of the claims on appeal require the presence or use of an "organic compound" defined only by way of a functional statement. While the specification sets forth a number of compounds stated to possess the claimed function, those compounds are strictly limited to those containing either a carbon-selenium bond or a carbon-sulfur bond. The genus of "organic compounds" is vast and overwhelms that subset of carbon-selenium and carbon-sulfur compounds described in the

specification of this application. Indeed, we believe that a person skilled in this art reading the claims and their requirement of use of an "organic compound" possessing the stated function would not immediately comprehend that such "organic compounds" are those that contain a carbon-sulfur or carbon-selenium bond since "organic compounds" are typically viewed as those containing carbon and hydrogen atoms.

In our view, the claims before us for review set forth "only a definition of a useful result rather than a definition of what achieves that result." Eli Lilly, 119 F.3d at 1568, 43 USPQ2d 1406. Accordingly, claims 1-57 are unpatentable under 35 U.S.C. § 112, first paragraph (written description).

Prior Art Rejections

In reaching his conclusion of obviousness, the examiner has determined that none of the three references applied individually explicitly describe the function that the claimed "organic compound" must possess. Rather, the examiner has made findings in regard to the properties that the organic compounds of interest in each of the references are stated to possess. For example, the examiner finds that the organic compounds in Mitoma "reduce background luminescence and increase sensitivity of measurement." Examiner's Answer, page 5. In regard to Kricka, the examiner determined that the organoboron compounds of that reference increase signal/background ratio with increasing concentration of the compounds. Id., page 6. The examiner determined that dithiothreitol agents of Wood increase the sensitivity of the assay. Id., pages 7-8.

In reviewing the examiner's obviousness rejections, it does not appear to us that the examiner considered the obviousness issue in light of the most relevant legal

standards. Here, each of the three references relied upon by the examiner involve the use of an "organic compound" in a luminescent assay wherein the organic compound affects the observed luminescence. However, none of the references describe the effect the organic compounds have on the observed luminescence in the terms required by the functional statement in the claims on appeal. It may be that the organic compounds described in each of the three references do in fact affect the observed luminescence in the manner required by the claims on appeal. However, that fact cannot be determined simply from a review of the words set forth in the references.

Under these circumstances, it has been held that it is proper for the USPTO to shift the burden to appellants to present objective evidence that the organic compounds described in each of the three references relied upon by the examiner do not possess the claimed function. As set forth in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977):

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on `inherency' under 35 U.S.C. § 102, on `prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].

While the court was discussing product claims in that portion of the opinion, the legal principle discussed therein applies equally to process claims. See, id., 562 F.2d at 1253, 195 USPQ 432-433.

Under these circumstances we find it appropriate to vacate the prior art rejections. Furthermore, consideration of the prior art rejections at this time may be premature as appellants may decide to amend the claims in response to the new grounds of rejection. Note that limiting the organic compounds of the claims to those containing carbon-sulfur or carbon-selenium bonds and excluding thiol group containing compounds from the claims would appear to make the three references relied upon by the examiner less relevant.

Time Period For Response

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

VACATED; 37 CFR § 41.50(b)

William F. Smith
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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) INTERFERENCES

Schwegman, Lundberg,
Woessner & Kluth, P.A.
P.O. Box 2938
Minneapolis, MN 55402

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